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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/614,685

07/03/2003

Yehoshua Shachar

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09/03/2008

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EXAMINER

GILBERT, ANDREW M

ART UNIT

PAPER NUMBER

3767

MAIL DATE

DELIVERY MODE

09/03/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/614,685	<b>Applicant(s)</b> SHACHAR, YEHOASHUA	
	<b>Examiner</b> ANDREW M. GILBERT	<b>Art Unit</b> 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-10,12-39 and 41-61 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,9,10,12-16,18,21,24,25,28-30,32,37-39,41-43,47,51 and 55-57 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 December 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

Continuation of Disposition of Claims: Claims withdrawn from consideration are 7, 8, 17, 19, 20, 23, 26, 27, 31, 34-36, 44-46, 48-50, 52-54 and 58-61.

## **DETAILED ACTION**

### ***Acknowledgments***

1. This office action is in response to the reply filed on 4/10/2008.
2. The Examiner notes that the proper status identifiers of the claims include the identifier "Withdrawn". In further communications, the examiner requests the Applicant submit claims with identifiers that label the withdrawn claims as "Withdrawn" as appropriate.
3. The applicant's amendments to the claims have obviated all previous claim objections and 35 USC 112 rejections.
4. Claims 1, 3-6, 9, 10, 12-18, 21, 22, 24, 25, 28-30, 32, 37-39, 41-43, 47, 51, and 55-57 are pending. The other claims are previous withdrawn or cancelled.

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 3, 5, 6, 12-16, 18, 22, 24, 25, 28, 29, 32, 33, 37, 38, 39, 41, 42, 43, 47, 48, 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soykan et al (6206914) in view of Patterson (6379323). Soykan et al discloses an implantable apparatus comprising: an implantable pouch (col 3, lns 6-31; col 8, lns 63-67; col 9, lns 38-60; col 10, lns 4-8; col 12, lns 51-65; col 13, lns 16-28; col 14, lns 26-39; col 15, lns

5-12; col 16, lns 23-27, lns 42-61) having multiple chambers composed of a bioabsorbable material, the pouch comprising a scaffolding (col 9, lns 9-37; wherein the stent is disclosed as being polymeric and bioabsorbable) capable of degrading over time, and a synthetic skin ( ) for enclosing the pouch; and multiple medicating agents disposed in said chambers (col 4, lns 18-32; col 8, lns 56-67, col 9, lns 35-37; col 9, lns 38-59, col 12, lns 51-65; wherein each of the microscopic containment vehicles forms a chamber and each of the containment vehicles is capable of containing various cells and therapeutic agents); multiple implantable piezoelectric pumps (col 4, lns 18-32; col 12, lns 51-65; col 13, lns 16-27; col 14, lns 26-39) fabricated in the pouch which forms a skeleton of the pumps, the pumps being configured to transfer medicating agents to said patient (col 4, lns 18-32; col 12, lns 51-65; col 13, lns 16-27; col 14, lns 26-39); and an implantable, biocompatible and bioabsorbable skin (col 9, lns 38-60, col 10, lns 4-col 11, lns 14) covering the pouch and pumps; and an implanted control circuit (col 4, lns 18-32, col 13, lns 16-27, col 14, lns 10-39, col 15, lns 4-24, col 16, lns 18-61) to control proper dosing and scheduling of said medicating agent in a closed loop control mode so that control of the operation of the system is performed autonomously as determined by locally sensed homeostatic parameters (col 3, lns 6-31; col 8, lns 63-67; col 9, lns 38-60; col 10, lns 4-8; col 12, lns 51-65; col 13, lns 16-28; col 14, lns 26-39; col 15, lns 5-12; col 16, lns 23-27, lns 42-61; and discussion below in Response to Arguments).

7. In reference to claims 3, 5, 6, 12-16, 18, 22, 24, 25, 28, 29, 32, 33, 37, 38, 39, 41, 42, 43, 47, 48, 55, 62-64 see (col 3, lns 6-31; col 5, lns 55-59; col 8, lns 63-67; col 9, lns 38-60; col 10, lns 4-8; col 12, lns 51-65; col 13, lns 16-28; col 14, lns 26-39; col 15,

Ins 5-12; col 16, Ins 23-27, Ins 42-61; discussion below in Response to Arguments; wherein the Examiner notes that the device of Soykan et al is fully capable of being placed in at a tumor cite and the sensing elements are fully capable of measuring pressure, temperature, pH, and various physiological properties that can be representative of the state of the tumor site to control agent release and furthermore the drug-eluting cells may be genetically engineered to produce a variety of therapeutic agents (col 8, Ins 19-27; additionally the Examiner notes that a pleiotrophic agent is merely an agent that produces many effects and Soykan et al discloses many agents that produce many effects in the body).

8. However, Soykan et al fails to teach collagen matrix scaffolding. Patterson teaches that it is known to have a scaffolding composed of collagen forming a matrix capable of degrading over time (col 4, Ins 28-51) for the purpose of maintain the device in a certain position in the body during treatment and then degrading to avoid surgical risks associated with removing the device after treatment. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the polymeric scaffolding as taught by Soykan et al with the collagen matrix scaffolding as taught by Patterson for the purpose of maintain the device in a certain position in the body during treatment and then degrading to avoid surgical risks associated with removing the device after treatment.

### ***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 3767

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 4, 9, 10, 21, 30, 56, and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soykan et al in view of Humes et al (2002/0090388). Soykhan et al discloses the invention substantially as claimed except for expressly disclosing delivering cytokine, chemotherapeutic agents to eliminate tumors. Humes et al teaches that it is known to have a drug delivery device delivering cytokine, chemotherapeutic agents ([011], [074], [075]) for the purpose of tumor elimination. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the agents as taught by Soykan with the cytokine and chemotherapeutic agents as taught by Humes et al for the purpose of delivering therapeutic agents for the purpose of tumor elimination.

### ***Response to Arguments***

11. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

12. Further, the Applicant argues that Soykan et al disclose or does not properly suggest:

- i. The implantable pouch having multiple chambers and multiple medicating agents.
- ii. A coating or film on a stent is not a skin enclosing a scaffolding to form a pouch for containing a medical agent.

- iii. Local control of the device – rather, the stimulation device 22 is not implanted and is remote from the device.

13. In response to the applicant's argument (i) the Examiner notes that the Applicant has not structurally defined the multiple chambers. The microscopic containment vehicles disclosed in Soykan et al are multiple chambers that house various medicating agents (see above citations). The Examiner recommends structurally defining the chambers.

14. In response to the applicant's argument (ii), the Examiner notes the Applicant has not structurally defined the 'skin' or materially classified the 'skin'. The coating or film covering the stent – which may be polymeric (see above citations), and the microscopic containment vehicles is fully capable of being considered a 'skin' and reads on the applicant's claim limitations.

15. In response to the applicant's argument (iii), the Examiner notes that the stimulation device 22 is implanted and "proximate" to the pumps. "Proximate" is very broad and may include implantable devices separate from the implantable pumps. The Examiner suggests structurally defining that the implanted control circuit is housed within the implantable pouch. Further, the Examiner notes that stimulation device "controls device operations" and has a microcomputer unit 78, processor 83, and memory 84, 86 (col 15). The stimulation device may be externally programmed, but the device during use is fully capable of autonomous closed loop control of the pumps as determined by locally sensed homeostatic parameters (see above citations).



***Conclusion***

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW M. GILBERT whose telephone number is (571)272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3767

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew M Gilbert/

Examiner, Art Unit 3767

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767